REMARKS

Withdrawn Claims

Claims 3, 4, 9-12, 15-22, 25, 26, and 29-32 have been cancelled as drawn to a non-elected invention.

Informal Matters

The first paragraph of the specification has been amended, as requested by the Examiner, to update the priority information. The Examiner has indicated that some documents on the information disclosure statement were not available for review. As requested, copies of these documents are enclosed.

The Double Patenting Rejection

The Examiner has provisionally rejected Claims 1, 2, 5, 6, 8, 13, 14, 23, and 24 as being unpatentable over Claims 1, 14, 16-19, 26, 27, and 29 of copending Application Ser. No. 10/093,845. The Examiner has also provisionally rejected Claims 1, 5-7, 13 and 23 over claims 1, 4, 10, 11, and 39 of copending Application Ser. No. 10/158,777. An obviousness-type double patenting rejection is appropriate when a claim merely defines an obvious variation of an invention claimed in a patent. M.P.E.P. § 804(II)(B)(1). A double-patenting rejection must rely on a comparison with the claims in an issued or to be issued patent. M.P.E.P. § 804(III).

The Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct as each set of claims is directed to a composition comprising a targeting moiety, a therapeutic agent, and a carrier. The Examiner reasons the claims of the pending applications differ in that an additional component is present, either a stabilizing agent, or additional therapeutic agents.

Applicants agree to submit a terminal disclaimer with respect to Application Ser. No. 10/093,845 and Application Ser. No. 10/158,777 when allowable subject matter is determined.

The Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 23, 24, 27, and 28 under 35 U.S.C. § 112, second paragraph. The second paragraph of Section 112 requires that the claims set out and

circumscribe a particular area which applicants regard as their invention with a *reasonable* degree of precision and particularity.

Specifically, the Examiner asserts that the claims are ambiguous because it is unclear what disease is being treated. Claim 23 has been amended to recite that that the disease associated with neovascularization is cancer, solid tumors, leukemias; tumor metastasis; benign tumors, hemangiomas, acoustic neuromas, neurofibromas, trachomas, and pyogenic granulomas; rheumatoid arthritis; psoriasis; chronic inflammation; ocular angiogenic diseases, diabetic retinopathy, retinopathy of prematurity, macular degeneration, corneal graft rejection, neovascular glaucoma, retrolental fibroplasia, rubeosis; arteriovenous malformations; ischemic limb angiogenesis; Osler-Webber Syndrome; myocardial angiogenesis; plaque neovascularization; telangiectasia; hemophiliac joints; angiofibroma; or wound granulation. Support for this amendment can be found, e.g., at page 29, lines 23-34 of the specification. Reconsideration is respectfully requested.

The Rejection under 35 U.S.C. § 102(b)

The Examiner has rejected Claims 1, 2, 5, 6, 13, 14, 23, and 24 under 35 U.S.C. § 102(b) as being anticipated by Lie, et al., U.S. Pat. No. 5,512,294. The Court of Appeals for the Federal Circuit has stated that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984); *Alco Standard Corp. v. Tennessee Valley Auth.*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991) (citations omitted). As explained in detail below, Applicant believes that the pending claims are not anticipated by the prior art relied upon by the Examiner.

The Examiner asserts that Li et al disclose targeting polymerized lipsosome contrast agents that may have attached antibodies for cellular receptors, and that the targeting group of the polymerized liposomes may be antibodies. The Examiner further asserts that Li discloses a composition comprising a targeting moiety, a linking carrier, and a therapeutic moiety, hence generating a composition comprising multiple antibodies.

Applicant respectfully traverses this rejection. Li, et al., is directed toward targeted polymerized liposome contrast agents; that is, agents for magnetic resonance imaging and radioisotope imaging or optical imaging. Li, et al., does not teach or suggest compositions useful for therapeutic purposes. Specifically, Li, et al., does not teach that the compositions contain a therapeutic moiety, including a therapeutic antibody. It is possible that the Li, et al., implies that multiple antibodies may be used in the composition; however, it is not taught that any of the antibodies are therapeutic moieties. Discussion of antibodies in Li, et al., is limited to antibodies which are targeting agents only.

Because Li, et al., does not describe a composition containing a therapeutic moiety, as required by Claim 1, Li, et al., can not anticipate Claim 1, or any claim dependent therefrom. Reconsideration is respectfully requested.

The Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1 and 6-8 under 35 U.S.C. § 103(a) as being unpatentable over Li et al., U.S. Patent No. 5, 512,294 in view of Klaveness, et al. U.S. Patent No. 6,261,537. The Examiner bears the burden of establishing a prima facie case of obviousness (Section 103). In determining obviousness, one must focus on Applicant's invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991). The primary inquiry is:

> whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success . . . . Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure.

In re Dow Chemical, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Specifically, the Examiner asserts that Li, et al., fails to bind to the $\alpha_v\beta_3$ site and disclose one the of the therapeutic antibodies set forth in Claim 1. The Examiner also asserts that Klaveness, et al. disclose microbubbles coupled to one or more vectors, including antibody vectors, such as ICAM-1, and further discloses receptors/targets associated with angiogenesis, such as $\alpha_v\beta_3$. The Examiner reasons that it would have been obvious to one of ordinary skill in the art as disclosed by Li, et al., to use an antibody that binds to the $\alpha_v\beta_3$ site as disclosed by Klaveness, et al. The Examiner further reasons that Li, et al., and Klaveness, et al. disclose targetable therapeutically active agents that may be linked to at least one vector (antibody) and both disclose the use of vectors

for vascular diseases, tumors, and/or angiogenesis, and therefore and considered to be in the same field of endeavor.

Applicant respectfully traverses this rejection. As explained above, Li, et al., does not disclose targetable therapeutically active agents. Li, et al. does discuss tumors and angiogenesis; however, the discussion is limited to a description of *in vivo* imaging of vascular tissue in the context of diagnosis and early evaluation of changes of the tissue in disease processes. There is no teaching or suggestion of therapeutic applications. Furthermore, Li, et al. is concerned with magnetic resonance, radioactive, or optical imaging, while the gas-filled microbubble compositions of Klaveness, et al. are suitable for ultrasound contrast agents. Applicant therefore submits that there is no motivation to combine Li, et al.,and Klaveness, et al., and the Examiner has not made a *prima facie* case of obviousness with regard to the disclosure of Li, et al., and Klaveness, et al.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

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